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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/825,661

04/16/2004

Peter K.T. Pang

2968-150

8482

6449 7590 12/27/2006  
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EXAMINER

BORIN, MICHAEL L

ART UNIT

PAPER NUMBER

1631

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
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3 MONTHS

12/27/2006

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 12/27/2006.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

**Office Action Summary**

Application No.

10/825,661

Applicant(s)

PANG ET AL.

Examiner

Michael Borin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10/13/2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 21-35 is/are pending in the application.
- 4a) Of the above claim(s) 26-30, 35 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 31-34 is/are allowed.
- 6) ☒ Claim(s) 21-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### **Status of Claims**

Amendment filed 10/13/2006 is acknowledged. Claims 21-35 are pending. Claims 26-30,35 remain withdrawn from further consideration.

Rejections and objections not reiterated from previous Office actions are hereby withdrawn. The following rejections constitute the complete set presently being applied to the instant application.

### ***Claim Rejections - 35 USC § 102 and 103.***

Claims 21-25 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C.103(a) as obvious over Dupont et al (US Patent 5,618,925).

The rejection is maintained for the reasons of record and further in view of the following response to applicant's arguments.

Applicant argues that one would not Dupont's extract to inherently have anti-PHF activity. In response, attorney's arguments can not replace factual evidence. Applicant's assertion does not provide sufficient evidence that the referenced product does not possess activity as claimed. Both the referenced and claimed extracts are aqueous extracts of shark cartilage. Where applicant claims a composition in terms of function, property or characteristic where said function is not explicitly shown by the reference, the burden is placed upon the applicant to provide clear evidence that the respective compositions do in fact differ.

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Applicant argues that that Dupont's method "does not include any steps that are potentially denaturing". First, it is not clear what applicant means by "potentially" denaturing. Second, by "denaturing" conditions are addressed in Dupont as presence of special reagents, such as guanidine or enzymes (col. 2, lines 33,34), rather than merely aqueous extraction used in Dupont's, as well as in instant methods. Third, the instant disclosure never mentions that the conditions of the instant method should be addressed as "denaturing", even if potentially denaturing. Contrary, the disclosure recites the full range of temperatures from 4° to 120° C as equivalently appropriate for the extraction (page 6, lines 10, 17).

Further, applicant attempts to contrast the claimed method as using spray drying compared to lyophilization. This is surprising as the original claims filed in the instant application were directed to lyophilizing rather than spray drying of the extract.

Furthermore, applicant seems to address Dupont's product as solid compared to liquid extract produced by the instant method. However, first, Dupont addresses extract as either liquid or solid (col. 3, lines 25-27 for example), and second, conversely, the extract obtained by spray drying, as in the instant invention, is in a solid form (see Maa reference submitted by the applicant, p. 284, second paragraph).

In addition, applicant asserts that spray drying is similar to lyophilization in that it has a "high potential for heat and surface denaturation". This allegation is not substantiated by a factual evidence; contrary, the Maa reference submitted by the applicant teaches that spray drying does not necessarily result in denaturation (p. 284, bottom).

Claims 21-25 are in product-by-process format and is are drawn to a shark cartilage extract prepared by extraction shark cartilage at 85-120°C for 2-4 hours, cooling the extract and separating supernatant from pellet by centrifugation. This supernatant (supernatant 1) is combined with the supernatant 2 obtained by the repeated extraction with water of the pellet remaining after supernatant 1 separation.

***Conclusion.***

8. Claims 31-34 directed to method of making shark cartilage extract are allowed. The prior art does not teach the method of making as claimed, namely a method comprising extraction of shark cartilage at 95-120°C for 2-4 hours, cooling the extract, separating supernatant from pellet by centrifugation and combining this supernatant (supernatant 1) with the supernatant 2 obtained by the repeated extraction with water of the pellet remaining after supernatant 1 separation.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Michael Borin, Ph.D.  
Primary Examiner  
Art Unit 1631